

C. Remarks

The claims are 1-41, with claims 1, 2, 19 and 20 being independent.

Applicants assume that claims 19-41 have been withdrawn from further consideration as being drawn to non-elected subject matter, though the Office Action does not reflect this. In addition, while claims 1-3, 6-8, 10 and 12-18 read on the elected species, claims 4, 5, 9 and 11 remain pending in the case as well. Claims 1-4, 6, 7 and 12-18 have been amended as to formal matters; Applicants submit that no new matter has been added (support can be found in the application as filed, e.g., paragraphs [0029]-[0031]). Reconsideration of the present claims is respectfully requested.

Claims 1-3, 6-8, 10 and 12-18 stand rejected under 35 U.S.C. §103(a) as being obvious over Borkan (U.S. Patent No. 4,935,243) or Hassan (WO 03/090726) in view of Tindal (U.S. Patent No. 6,387,400) and Tanner (U.S. Patent No. 6,340,473). Applicants respectfully traverse this rejection.

The present invention is directed to an edible, chewable, soft gelatin capsule; importantly, the capsule shell is formed from a capsule film having a wet mass comprising at least gelatin, hydroxypropylated starch and glycerol. By virtue of this constitution, it is possible to provide high water content, chewable soft gelatin capsules with improved organoleptic properties, i.e., improved sensory impressions to potential users. The present invention allows for the manipulation of the origin, bloom strength and melting points of gelatins and mixtures of gelatins, the use of substantially ungelatinized starch as a water retention agent, the fabrication of thinner than expected gelatin films for use in the encapsulation process, only partial drying to a high end water content and dusting of the capsules with an anti-stickiness surface treatment agent.

Borkan discloses a chewable softgel capsule containing gelatin and a plasticizer (including glycerol); however, as noted by the Examiner, Borkan contains no teaching or suggestion with regard to the inclusion of a starch or other water retentive agent in an ungelatinized or crystalline form. The hydrogenated starch hydrolysate used therein (described at column 4, line 5, to column 5, line 11) is characterized as a mixture of sugars, hydrogenated sugars, polyols and sugar alcohols. This component in no way equates with the high molecular weight, polymeric starch employed in the subject invention.

Hassan likewise relates to a chewable softgel capsule, which incorporates a matrix or fill system, which is gelled or semi-gelled, formed from a low bloom strength gelatin, a gelatin modifier and, in some cases, a hydrolyzed gelatin. This matrix is then encapsulated in a relatively conventional sheath or outer capsule shell. Here again, as indicated by the Examiner, Hassan contains no teaching or suggestion of the addition of a starch or other water retentive agent or any matrix forming component in an ungelatinized or crystalline form to the capsule shell as required by the subject invention. In addition, the capsule sheath of Hassan utilizes a lower bloom strength of gelatin (see Examples 8 and 9) at 100 bloom than typically used for the subject invention (see Table 12 of present application; bloom strength of from 150 to 275). Clearly Hassan addresses a technology very different from the present invention, i.e., a softgel with a gelled fill material; as a result, one of ordinary skill in the art would unlikely turn to Hassan and arrive at the subject invention.

Tindal does not remedy the deficiencies of Borkan and Hassan. The Examiner alleges that Tindal provides the missing hydroxypropylated starch (HPS) component, but Tindal contains only a passing reference to HPS as one of a number of possible components for the casing or shell material. There is no reference to the use of the

HPS in an ungelatinized or partially crystallized form. Furthermore, Tindal more generally relates to the partial neutralization of a drug incorporated into a fill system by the addition of sequential aliquots of the neutralizing agent. There is no teaching or suggestion of a particular shell composition suitable for a chewable capsule. The Examiner has incorrectly cited the passage at column 5, line 38, of Tindal as evidence for the use of glycerol as a plasticizer; the disclosed use here is in the fill material, where the glycerol is employed as a co-solvent with polyethyleneglycol for the active pharmaceutical agent. As with Hassan, one of ordinary skill in the art would not rely on this reference for any teachings related to the formulation of a chewable softgel shell.

Tanner likewise fails to remedy the deficiencies of Borkan and Hassan.

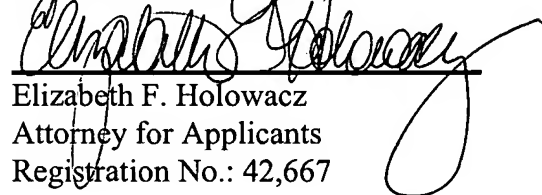
Tanner discloses capsule shell compositions comprising iota carrageenan, modified starch (including HPS) and plasticizer (including glycerol). There is no reference to the use of gelatin and, indeed, the disclosure states that the intention is to obviate the requirement for gelatin. As such, this reference teaches away from the present invention wherein modified starch and plasticizer are combined with gelatin. In other words, one of ordinary skill in the art would not be motivated to achieve the subject invention (which utilizes gelatin) from this reference.

In sum, the presently claimed invention is not rendered obvious by the cited combination of references. Both Borkan and Hassan fail to disclose or suggest at least the use of hydroxypropylated, substantially ungelatinized starch, while Tindal and Tanner fail to remedy at least that basic deficiency. Tindal is directed to the manufacture of a capsule fill system (not a capsule itself), and Tanner teaches away from the invention. For at least these reasons, Applicants submit that the present invention is not rendered obvious and respectfully request withdrawal of the §103 rejection.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,


Elizabeth F. Holowacz
Attorney for Applicants
Registration No.: 42,667

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200

FCBS_WS 2160732v1